

February 18, 2022

## RE: Update to Pre-Collection Device Shelf Life

Dear Valued Customer,

We are providing this notification to advise you of a finding related to the following product(s) you have ordered from us.

### Product affected:

Product name	ORAcollect™•DNA
Catalog number/SKU	OCR-100

### Background:

Routine internal testing at DNA Genotek Inc. (“DNA Genotek”) determined that certain manufactured products, listed above, may experience higher-than-expected stabilizing liquid evaporation. As a result, in a small subset of products, the amount of available stabilizing liquid may be lower than expected. This may impact the current “Collect sample by/Use by” date (i.e. the shelf life), which is indicated on the collection device tube label. DNA Genotek internal data shows that despite the potential increase in evaporation, the performance of the device relating to DNA collection, stability and DNA quality is not impacted. DNA concentration may be higher than expected. Additionally, to date there have been no reports from customers or users that indicate impact on the safety or performance of products listed above.

### Action taken by manufacturer:

DNA Genotek has identified the cause and is taking steps to correct this issue. We are informing you of this quality issue so that you can assess and understand the potential impact to your processes. Additionally, we are notifying the appropriate regulatory agencies as required.

### Action(s) to be taken by customer or user:

DNA Genotek recommends the following actions, depending on the scenario that applies to you:

**1. You have successfully processed samples using these products:**

- No action is required.

**2. You have unused products:**

- The pre-collection shelf life has been reduced by 12 months. You should use the products by the date that is 12 months prior to the “Collect sample by/Use by” date listed on the collection device tube label.

**3. You have ordered products but have not received them:**


- The pre-collection shelf life has been reduced by 12 months. You should use the products by the date that is 12 months prior to the “Collect sample by/Use by” date listed on the collection device tube label. Should there be any delay in the shipment or delivery of your order, your account manager will reach out to you.

**4. The processing lab is having difficulty recovering the minimum input volume required for the sample extraction:**

- If you do not have sufficient volume for your workflow, contact our Technical Support team at [support@dnagenotek.com](mailto:support@dnagenotek.com).

Please acknowledge receipt of this advisory letter by completing this [ONLINE FORM](#). Should you have additional questions or concerns pertaining to this letter, contact your DNA Genotek account manager or, for technical assistance, contact our Technical Support team at [support@dnagenotek.com](mailto:support@dnagenotek.com).

Sincerely,

  
Regulatory Affairs, DNA Genotek



February 18, 2022

## RE: Update to Pre-Collection Device Shelf Life

Dear Valued Customer,

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### Product affected:

Product name	ORAcollect™•Dx, ORAcollect™•RNA
Catalog number/SKU	OCD-100, OCD-100A, ORE-100

### Background:

Routine internal testing at DNA Genotek Inc. (“DNA Genotek”) determined that certain manufactured products, listed above, may experience higher-than-expected stabilizing liquid evaporation. As a result, in a small subset of products, the amount of available stabilizing liquid may be lower than expected. This may impact the current “Collect sample by/Use by” date (i.e. the shelf life), which is indicated on the collection device tube label. DNA Genotek internal data shows that despite the potential increase in evaporation, the performance of the device relating to DNA collection, stability and DNA quality is not impacted. DNA concentration may be higher than expected. Additionally, to date there have been no reports from customers or users that indicate impact on the safety or performance of products listed above.

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Regulatory Affairs, DNA Genotek